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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/677,967 | 10/02/2003 | Anke Esperester | 1/1556 | 9274 |
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| MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368 | | | EXAMINER KIM, JENNIFER M | |
| | | | ART UNIT 1617 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/677,967 | Applicant(s) ESPERESTER ET AL. | |
| | Examiner Jennifer Kim | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed on July 17, 2007 have been received and entered into the application.

Action Summary

The rejection of claims 7-11 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19 of U.S. Patent No. 6,663,889 B1 is being maintained for the reasons stated in the previous Office Action.

The rejection of claim 7 under 35 U.S.C. 102(b) as being anticipated by Weiser (2000) is being maintained for the reasons stated in the previous Office Action.

The rejection of claims 7-11 under 35 U.S.C. 102(b) as being anticipated by Maerz et al. (WO 01/05378A1) (see English translation U.S. Patent No. 6,663,889B1) is being maintained for the reasons stated in the previous Office Action.

The rejection of claims 7-11 under 35 U.S.C. 102(e) as being anticipated by Maerz et al. (U.S. Patent No. 6,663,889 B1) is being maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicants' arguments filed July 17, 2007 have been fully considered but they are not persuasive. **With regard to the non-statutory obviousness-type double patenting rejection**, Applicants argue that one skilled in the art at the time of the invention would not conclude that ambroxol could be used for treating inflammation of the pharynx because at the time of the present invention, as described in the instant Application, *in vitro* and *in vivo* studies of the anti-inflammatory effect of ambroxol were open to interpretation and contradictory. This is not found persuasive because the issue not whether the anti-inflammatory effect of ambroxol were open to interpretation and contradictory at the time of the invention; the **effect is unavoidable** in view of patented claim 19, encompassing the same method steps as the instant claims. It is noted that the obvious double patenting rejection made in the previous Office Action was made because the two sets of claims involve the same method steps administering the same composition. Patented claim 19 is drawn to a method of administering ambroxol to **a patient** comprising administering to the patient **a tablet for sucking** comprising **ambroxol**, a sugar alcohol as a matrix material, a pharmaceutically acceptable laminar silicate and a polyethylene glycol, optionally together with one ore more other pharmaceutical excipients, including taste enhancers or flavorings. The specific subject populations to be treated are not identified in the patented claim. Likewise, a specific subject population to be treated is not identified in the instant claims. Thus claims in the instant Application and the patented claim encompass the

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same method step of administering the same active agents to the same unspecified subject population.

With regard to the 102(b) rejection of claim 7 as being anticipated by Weiser, Applicants argue that in light of the state-of the art at the time the invention was made, Weiser would not have been understood by one skilled in the art to support the Examiner's statement in the rejection that Weiser teaches ambroxol for the treatment of a sore throat because Weiser is not an enabling disclosure of the present invention as claimed. This is not found persuasive because Weiser et al. clearly teach that ambroxol is well established for the treatment of inflammatory disease of the respiratory tract and can be used as an effective treatment for a sore throat because the compound has local anesthetic properties. Accordingly, this teaching clearly meets all the requirements set forth in instant claim 7. The examiner has provided the state-of-the-art at the time the invention was made, namely Weiser, to show that Applicants' claimed invention is well known over 1 year prior to the filing of Applicants' invention. Further, Applicants have not provided any evidence to show why the teaching of Weiser regarding the same criteria recited in instant claim 7 would not be enabled.

With regard to the 102(b) rejection of claims 7-11 anticipated by the Maerz WO publication; and the 102(e) rejection of claims 7-11 anticipated by Maerz '889 patent, Applicants argue that the instant invention is not inherently anticipated by the Maerz WO publication nor anticipated by the Maerz '889 because, again, at the time of the claimed invention, the *in vitro* and *in vivo* studies of the anti-inflammatory effect of

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ambroxol were open to interpretation and contradictory. This is not found persuasive because, again, regarding these rejections, the issue is not whether the anti-inflammatory effect of ambroxol were open to interpretation and contradictory at the time of the invention; **the effect is unavoidable** in view of the cited art drawn to the employment of the same method steps as the instant claims. The specific subject populations to be treated are not identified in any of the claims. Thus, the prior art concerns the same method step of administering the same active agents to the same unspecified subject as the instant claims. Claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of January 17, 2007 is deemed proper and asserted with full force and repeated herein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19 of U.S. Patent No. 6,663,889 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claim encompasses same method step of administering the same active agent to the same patient as instantly claimed. The claim in the patent is drawn to the same method of administering ambroxol to a patient comprising administering to the patient a tablet for sucking comprising ambroxol, a sugar alcohol as a matrix material, a pharmaceutically acceptable laminar silicate and polyethylene glycol, optionally together with one or more other pharmaceutical excipients. (see claim 19, examples in column 3). Accordingly, the claimed treatment of inflammation in the pharynx and reduction of the redness in the throat is obviously achieved by the same method steps of administering the same active agent to the same subject in the patented claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Weiser (2000).

Weiser teaches that Ambroxol is well established in the treatment of inflammatory diseases of the respiratory tract. Weiser teaches that Ambroxol can be used as an effective treatment of sore throat (pharynx). (abstract).

Claims 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Maerz et al. (WO 01/05378A1) (see English translation U.S. Patent No. 6,663,889B1).

Maerz et al. teach a tablet for sucking containing the active substance ambroxol and having improved properties brought by peppermint flavor, saccharin, sorbitol (sugar alcohol), polyethylene glycol (Macrogol 6000) and hydrated magnesium silicate.

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(abstract, examples on pages 5-6) (abstract, examples in column 3 and claims, English version).

Applicants' recitation in claims 7-11 of treating inflammation in the pharynx and thereby reducing redness would be an inherent effect of the same method steps administering the same active composition to the same subject taught by the prior art.

Claims 7-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Maerz et al. (U.S. Patent No. 6,663,889 B1).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Maerz et al. teach a method of administering ambroxol to a patient comprising administering to the patient a tablet for sucking comprising ambroxol, a sugar alcohol as a matrix material, a pharmaceutically acceptable laminar silicate and a polyethylene glycol, optionally together with one or more other pharmaceutical excipients. (see claim 19, examples on column 3).

Applicants' recitation in claims 7-11 of treating inflammation in the pharynx and thereby reducing redness would be an inherent effect of the same method steps administering the same active composition to the same subject taught by the prior art.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
August 31, 2007